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Attorney's Docket No.: 17084-004016/24601-4020

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gyula Hadlaczky, et. al
Serial No. : 10/782,129
Filed : February 18, 2004
Cust. No. : 20985
Title : ARTIFICIAL CHROMOSOMES, USES THEREOF AND METHODS FOR
PREPARING ARTIFICIAL CHROMOSOMES

Art Unit : 1632
Examiner : Unknown
Conf. No. : 5795

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement and Forms PTO-1449 (2 pages), and cited references for filing in connection with the above-identified application. Because this Supplemental Information Disclosure Statement is filed prior to receipt of a first office action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:



The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie L. Seidman
Reg. No. 33,779

Attorney Docket No. 17084-004016/24601-4020

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CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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Date of Deposit July 30, 2004

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie L. Seidman



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed before the receipt of the First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, if it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (2 pages) and copies of the cited references are provided herewith in connection with the above-captioned application.

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Stephanie L. Seidman

The documents listed on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items are necessary.

Since the last Information Disclosure Statement was filed on May 21, 2004, no additional co-pending applications need be made known to the Examiner.

The Examiner's attention is directed to the cited reference Oberle *et al.* (*Biochimica et Biophysica Acta* (2004) 1676:223-230). Oberle *et al.* describes methods for delivering artificial chromosome expression systems (ACEs) to cells. Specifically, Oberle *et al.* demonstrates that when cells are treated with ultrasound energy and the cationic lipid SAINT-2 or DOTAP prior to contacting them with ACEs, the ACEs are delivered into the cells. Oberle *et al.* states that, prior to its publication, there was no suitable procedure for delivering ACEs into cells because the size of the ACEs was too large to allow internalization of ACEs complexed with cationic lipids or polymers (see, *e.g.*, Abstract at page 223 and page 224, col. 1, para. 3). Oberle *et al.* further states that incubation of ACEs with cationic lipids such as SAINT-2 and DOTAP to prepare ACEs/lipid complexes leads to partial unraveling of the ACEs with a loss of their condensed structure (see page 225, col. 1, para. 2). Oberle *et al.* does not provide any data to support these statements.

The instant application, as well as in U.S. Patent No. 6,743,967, which is a parent application of the instant application, however, describes the introduction of artificial chromosomes, including ACEs, into cells by lipid-mediated transfection (see, *e.g.*, p. 8, line 15; p. 23, line 26; p. 32, line 12; p. 34, line 15; p. 35, lines 23 and 28; p. 52, line 23, and p. 105, line 23; and p.117, lines 6 and 22 of the instant application).

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. 1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. 1.56(b) exists.

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Supplemental Information Disclosure Statement
Page : 3 of 3

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Applicant respectfully requests that the Examiner review the foregoing references and make them of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie L. Seidman
Reg. No. 33,779

Attorney Docket No. 17084-004016/24601-402O

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Substitute Form PTO-1449 (Modified) List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17084-004016 (24601-4020)	Application No. 10/782,129
	Applicant Gyula Hadlaczky, et. al		
	Filing Date February 18, 2004	Group Art Unit 1632	

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	NONE						

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	NONE							

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AA	Choo, K.H.A., "Turning on the centromere", <i>Nature Genetics</i> 18:3-4 (1998)
	AB	Eyestone, "Production and breeding of transgenic cattle using in vitro embryo production technology", <i>Theriogeneology</i> 51:509-517 (1999)
	AC	Fabb <i>et al.</i> , "Generation of novel human MHC class II mutant B-cell lines by integrating YAC DAN into a cell line homozygously deleted for the MHC class II region", <i>Human Molecular Genetics</i> 6(8):1295-1304 (1997)
	AD	Featherstone and Huxley, "Extrachromosomal maintenance and amplification of yeast artificial chromosomes", <i>Genomics</i> 17:267-278 (1993)
	AE	Financsek <i>et al.</i> , "Human ribosomal RNA gene: Nucleotide sequence of the transcription initiation region and comparison of three mammalian genes", <i>Proc. Natl. Acad. Sci.</i> 79: 3092-3096 (1982)
	AF	Gonzalez and Schmickel, "The human 18S ribosomal RNA gene: Evolution and stability", <i>Am. J. Hum. Genet.</i> 38: 419-427 (1986)
	AG	Gonzalez <i>et al.</i> , "Variation among human 28S ribosomal RNA genes", <i>Proc. Natl. Acad. Sci. USA</i> 82:7666-7670 (1985)
	AH	Hoffman <i>et al.</i> , "Lipochromosomes mediated gene transfer: identification and probable specificity of localization of human chromosomal material and stability of the transferents", <i>In Vitro</i> 17(8):735-740 (1981)
	AI	Huxley, "Mammalian artificial chromosomes and chromosome transgenics", <i>Trends in Genetics</i> 13(9):245-147 (1997)

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 17084-004016 (24601-4020)		Application No. 10/782,129	
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				Filing Date February 18, 2004		Group Art Unit 1632	
Other Documents (include Author, Title, Date, and Place of Publication)							
Examiner Initial	Desig. ID	Document					
	AJ	Lebo <i>et al.</i> , "Design and operation of a dual laser chromosome sorter", <i>Cytometry</i> 3:213-219 (1982)					
	AK	McCallum and Maden, "Human 18S ribosomal RNA sequences inferred from DNA sequence," <i>Biochem J.</i> 232:725-733 (1985)					
	AL	Moreadith <i>et al.</i> , "Gene targeting in embryonic stem cells: the new physiology and metabolism", <i>J. Mol. Med.</i> 75:208-216 (1997)					
	AM	Mukherjee <i>et al.</i> , "Entrapment of metaphase chromosomes into phospholipid vesicles (lipochromosomes): Carrier potential in gene transfer", <i>Proc. Natl. Acad. Sci. USA</i> 75(3):1361-1365 (1978)					
	AN	Nazar <i>et al.</i> , "Sequence homologies in mammalian 5.8S ribosomal RNA", <i>Biochem.</i> 15(3):505-508 (1976)					
	AO	Oberle <i>et al.</i> , "Efficient transfer of chromosome-based DNA constructs into mammalian cells," <i>Biochimica et Biophysica Acta</i> 1676: 223-30 (2004)					
	AP	Orkin, S.H., Report and Recommendations of the Panel to Assess the NIH Investment in Research of Gene Therapy, December 7, 1995, pages 1-45. Available online at: http://www.nih.gov/news/panelrep.html					
	AQ	Parkman <i>et al.</i> , "Abstract for: Gene Therapy for adenosine deaminase deficiency", <i>Annual Rev. Med.</i> 51 33-47 (2000)					
	AR	Safrany and Hidvegi, "New tandem repeat region in the non-transcribed spacer of human ribosomal RNA gene", <i>Nucl. Acids Res.</i> 17(8):3013-3023 (1989)					
	AS	Smith and Rubin, "Functional screening and complex traits: human 21q22.2 sequences affecting learning in mice", <i>Human Mol. Genet.</i> 6(10):1729-1733 (1997)					
	AT	Stubblefield and Pershouse, "Direct formation of microcells from mitotic cells for use in chromosome transfer", <i>Somatic Cell and Molec. Genet.</i> 18:485-491 (1992)					
	AU	Verma and Somia, "Gene Therapy – promises, problems and prospects", <i>Nature</i> 389:239-242 (1997)					
	AV	Vile, R.G., "Abstract of: Cancer Gene Therapy: Hard Lessons and New Courses", <i>Gene Therapy</i> 7(1):2-8 (2000)					
	AW	Wells <i>et al.</i> , "Production of cloned lambs from an established embryonic cell line: A comparison between in vivo- and in vitro-matured cytoplasts", <i>Biology of Reproduction</i> 57:385-390 (1997)					

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	